IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FT. WORTH DIVISION

ROBERT. B BROWN,	)	
	)	
Plaintiff,	)	Case No._____
vs.	)	
	)	JURY DEMANDED
EXACTECH, Inc. and	)	
EXACTECH US, Inc.,	)	
	)	
Defendants.	)	

COMPLAINT

COMES NOW the Plaintiff, Robert B. Brown, by and through undersigned counsel and submits this Complaint and Jury Demand against Exactech, Inc. ("Exactech") and Exactech US, Inc. ("Exactech US") (collectively as "Defendants"), for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff Robert B. Brown as a result of his injuries suffered as a direct and proximate result of Defendants' designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, failing to warn, warranting and/or selling a defective hip replacement system described as "AcuMatch M-Series Femoral Stem Component" ("Defective Device").

In support, Plaintiff alleges the following:

I. PARTIES

1. Plaintiff Robert B. Brown is currently a resident of Maryville, Blount County, Tennessee. Beginning in May of 2016, Plaintiff was a resident of Fort Worth, Texas, employed as an independent contractor on a long term employment contract.

2. Defendant Exactech, Inc. is a for profit Florida corporation organized and existing with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Exactech's stated business purpose is to "develop, manufacture, market, distribute and sell orthopaedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and internationally and to introduce its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities.

3. Defendant Exactech US, Inc. is a wholly subsidiary of Defendant Exactech, Inc., is a for-profit Florida corporation organized and existing under with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Defendant Exactech, Inc.'s "U.S. sales and distribution activities are conducted by [its] wholly owned subsidiary Exactech US, Inc." and Exactech U.S., Inc. is engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing its products, including the Defective Device into interstate commerce, either directly or indirectly through third parties or related entities. Collectively, Exactech, Inc. and Exactech US, Inc. are referred to in this pleading as "Exactech" or "Defendants."

II. JURISDICTION AND VENUE

4. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and no Defendant is a citizen of the same state as Plaintiff.

5. Venue is proper in this Court under 28 U.S.C. § 1391(c) because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

III. INTRODUCTION AND SUMMARY OF ACTION

6. Plaintiff alleges on information and belief against Exactech, Inc., and Exactech US, Inc. the following:

7. Defendants manufactured and distributed the Exactech Hip Implant Device ("Exactech Device") described as AcuMatch M-Series Femoral Stem. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, failed to warn, warranted and/or sold the Defective Device. Defendants stated in their 2002 annual report:

"Surgeons count on Exactech to understand their needs like no other company can. Founded and led by an orthopaedic surgeon, Exactech has an end-user's perspective on product development. Its implants and instrument systems are safe, effective and easy to use."

8. A defectively designed and manufactured AcuMatch M-Series Femoral Stem hip implant device left the possession of Defendants in a defective condition. Defendants delivered the Defective Device into the stream of commerce and allowed it to be implanted in a total hip arthroplasty in Plaintiff.

9. As a direct and proximate result of Defendants placing the Defective Device into the stream of commerce, Plaintiff required a hip replacement revision surgery.

10. As a direct and proximate result of Defendants placing the Defective Device into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; past, present and future medical, hospital, rehabilitative and pharmaceutical expenses; and other related damages.

IV. FEDERAL REQUIREMENTS

11. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

12. Pursuant to federal law, a device is deemed misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health if used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

13. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to a death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to a death or serious

injury. Federal law also requires the FDA to establish regulations requiring a manufacturer of a medical device to promptly report to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation federal law which may present a risk to health. See 21 U.S.C. § 360i.

14. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe, effective and otherwise in compliance with federal law. See 21 U.S.C. §360j(f).

15. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 et seq. The Federal Register explains that the Current Good Manufacturing Practice (CGMP) regulations do not prescribe the details of how a manufacturer must produce a device because the regulations must apply to a variety of medical devices. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing process employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

16. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provisions in section 820 renders a device adulterated under section 501(h) of the Act. See 21 U.S.C. § 351.

17. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR § 820.3(v).

18. Pursuant to 21 CFR § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

19. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

20. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

21. Pursuant to 21 CFR § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

22. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, batches, or their equivalents. Design validations shall ensure that the devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

23. Pursuant to 21 CFR § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

24. Pursuant to 21 CFR § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation.

25. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

26. Pursuant to 21 CFR § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification method, process, or procedure.

27. Pursuant to 21 CFR § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control systems to verify that the system, including necessary equipment, is adequate and functioning properly.

28. Pursuant to 21 CFR § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or products by substances that could reasonably be expected to have an adverse impact on quality.

29. Pursuant to 21 CFR § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately

designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

30. Pursuant to 21 CFR § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality in order to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

31. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer is required to validate computer software for its intended use according to an established protocol.

32. Pursuant to 21 CFR § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer must establish and maintain procedures to ensure that equipment is calibrated, inspected, checked, and maintained.

33. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspections and testing, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing, by objective evidence, that a process consistently produces a result or product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

34. Pursuant to 21 CFR § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring internal processes and establish control of process parameters for

validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified persons.

35. Pursuant to 21 CFR § 820.90, each manufacturer also must establish and maintain procedures to control products that do not conform to specified requirements.

36. Pursuant to 21 CFR § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventative actions.

37. Based on information and belief, Defendants' hip implant devices are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage or installation and are not in conformity with federal requirements. See 21 U.S.C. § 351.

38. Based on information and belief, Defendants' hip implant device was misbranded because, among other things, it was dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

39. Based on information and belief, Defendants' hip implant device was adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain CGMP for its hip implant devices in accordance with 21 CFR § 820 et seq., as set forth above.

40. Based on information and belief, Defendants failed to establish and maintain CGMP with respect to quality audits, quality testing and process validation for its hip implant devices.

41. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' hip implant devices were defective and failed, resulting in injuries to Plaintiff.

42. If Defendants had complied with the federal requirements regarding CGMP, Defendants' hip implant devices would have been manufactured properly and would not have resulted in injuries to Plaintiffs.

V. STATEMENT OF FACTS

43. On September 14, 2001, Plaintiff Robert B. Brown, electively underwent a left total hip arthroplasty procedure with the Exactech Device being implanted by Orthopedic Surgeon Dr. Brian Covino.

44. Prior to the surgery, Dr. Covino advised Plaintiff that the Exactech Device had an expected 15-20 year life span with the most likely mode of failure being wear of the polyethylene liner of the acetabular component. It would not have been expected the femoral stem to have failed in such a manner nor would Plaintiff have been warned that such a failure could occur. Dr. Covino was advised, directly or indirectly, by Defendants, their agents or employees, that the device would have the expected life span of 15-20 years and that the stem should never fail as it did.

Expert testimony will be presented at trial that it was the standard of medical care to advise a hip replacement patient that the implant should last 15-20 years, that there was no reasonable belief to believe that the stem component would *ever* fail in the manner in which the device failed.

45. Based upon the advice and recommendations of Dr. Covino, Plaintiff underwent successful hip replacement surgery. Plaintiff, relying, on this medical advice about the nature of the implant device, recovered and continued his life in normal fashion. Plaintiff did not use a device to assist in walking, nor did he modify his work, social, and physical lifestyle as he believed the device would function and last as he was advised. Had Plaintiff known of the potential failure, he would have elected to use a different device.

46. On or about June 5, 2016, Plaintiff was exiting his vehicle when the femoral stem of the device sheared and broke in half without warning or any intervening aggravating circumstance. Plaintiff suffered excruciating pain and was subsequently admitted to Baylor All Saints Medical Center wherein a total hip revision surgery was conducted. Plaintiff remained at Baylor All Saints Medical Center Inpatient Rehabilitation Center in Texas until his release on June 21, 2016 with home care services provided by the hospital.

47. Plaintiff took possession of the defective device and now having allowed it be inspected by experts, Plaintiff intends to prove that the device stem sheared off as a result of a defect in the manufacturing and/or design of the device. There is no medical basis for the stem to break as it did.

48. Plaintiff has learned that the device has failed in a like and similar manner after his surgery. This failure was reported to MAUDE[1] on December 10, 2007, wherein a patient was "stepping of an airplane and placed weight on his left leg" and underwent a revision because of a

[1] The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

fracture in the modular stem. Defendants were placed on notice of this defect and failed to warn Plaintiff, his physicians, or anyone of the defect and potential for failure of the stem.

As a result of the above, Plaintiff suffered tremendous loss, due to the faulty and defective nature of the Exactech Device and to the failure of Defendants to properly warn him and his physicians about the Exactech Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn him and his physicians about the Exactech Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Exactech Device.

49. All of the injuries and complications suffered by Plaintiff was caused by the defective design, lack of adequate warnings, construction and unreasonably dangerous character of the Exactech Device that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Exactech Device, Plaintiff would not have consented to the Exactech Device being used in his total hip arthroplasty. Moreover, Plaintiff could have electively addressed the potential need for revision, rather than suffer from the unknown catastrophic failure.

50. Consequently, because of Defendants' acts and omissions, Plaintiff has been harmed as a result of the Defendants' wrongful acts and omissions and files this suit to recover his damages, as described below.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

A. NEGLIGENCE

51. Plaintiff Robert B. Brown hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

52. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Exactech Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects.

53. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Exactech Device into interstate commerce. Defendants knew or should have known that those individuals who had the device surgically implanted were at risk for suffering harmful effects from it, including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Additionally, Defendants knew or should have known about the harmful effects from the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

54. The negligence of Defendants, their agents, servants and employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Exactech Device in a manner which was dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating and promoting the Exactech Device without adequately, sufficiently or thoroughly testing it;

c. Not conducting a sufficient testing program to determine whether or not the Exactech Device was safe for use;

d. Marketing and selling the Exactech Device when Defendants knew or should have known that it was unsafe and unfit for use because of the dangers to its users;

e. Selling the Exactech Device without proper and sufficient testing to determine the dangers to its users;

f. Negligently failing to adequately and correctly warn Plaintiff or her physicians, hospitals and healthcare providers of the dangers of the Exactech Device;

g. Negligently failing to recall their dangerous and defective Exactech Device at the earliest date that it became known that the device was, in fact, dangerous and defective;

h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come in contact with, and more particularly, implant the Exactech Device into their patients;

i. Negligently advertising and recommending the use of the Exactech Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Exactech Device was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently representing that the Exactech Device offered low wear and high stability, when, in fact, the opposite was true;

l. Negligently manufacturing the Exactech Device in a manner that was dangerous to those individuals who had it implanted;

m. Negligently producing the Exactech Device in a manner that was dangerous to those individuals who had it implanted;

n. Negligently assembling the Exactech Device in a manner, that was dangerous to those individuals who had it implanted;

o. Negligently under-reporting, underestimating and downplaying the serious dangers of the Exactech Device.

55. Defendants were further negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Exactech Device in that they:

a. Failed to use due care in designing and manufacturing the Exactech Device so as to avoid the risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Exactech Device; and

e. Were otherwise careless and negligent.

56. Despite the fact that Defendants knew or should have known that the Exactech Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and sell the Exactech Device.

57. Defendants knew or should have known that consumers, such as Plaintiff Robert B. Brown, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

58. Defendants' negligence was the proximate cause of Brown's physical, mental and emotional injuries and harm, and economic loss, which he has suffered and will continue to suffer.

59. By reason of the foregoing, Plaintiff Robert B. Brown experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Plaintiff also needed a revision surgery to replace the device, which carried the attendant risks of complications and death from such further surgery.

60. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

SECOND CLAIM FOR RELIEF

B. STRICT LIABILITY—FAILURE TO WARN

61. Plaintiff Robert B. Brown hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

62. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Exactech Devices. The Exactech Device that was implanted in Plaintiff was in substantially the same condition at the time that it was implanted as it was when it left Defendants' possession and entered into the stream of commerce.

63. The Exactech Device placed into the stream of commerce by Defendants and implanted in Plaintiff was defective because it was not accompanied by an adequate warning

64. In particular, Defendants knew or should have known that the Exactech device was subject to early failure and could cause elevated levels of cobalt and/or chromium, metallosis, damage to surrounding tissues, and other complications. Such failure or complications in turn may give rise to physical injury, pain and suffering, debilitation and the need for a revision surgery to replace the device, he the attendant risks of complications and death from such further surgery. Defendants failed to give consumers and physicians adequate warning of such risks

65. The Exactech Devices placed into the stream of commerce by Defendants were defective due to inadequate warnings, because Defendants knew or should have known that the Exactech Devices could fail early in patients and therefore give rise to physical injury, pain and suffering, debilitation and the need for a revision surgery to replace the device, with the attendant

risks of complications and death from such further surgery, but Defendants failed to give consumers and physicians adequate warning of such risks.

66. The Exactech Devices placed into the stream of commerce by Defendants were surgically implanted in a manner reasonably anticipated by Defendants.

67. As a direct and proximate result of Defendants' placement of the defective Exactech Devices into the stream of commerce, Plaintiff Robert B. Brown experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Plaintiff also needed a revision surgery to replace the device, which carried the attendant risks of complications and death from such further surgery.

68. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

THIRD CLAIM FOR RELIEF

C. STRICT LIABILITY-DESIGN DEFECT

69. Plaintiff Robert B. Brown hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

70. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the Exactech Devices that were surgically implanted in Plaintiff Robert B. Brown.

71. At all times herein mentioned, the Exactech Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective, and unreasonably dangerous condition, which was dangerous to users such as Brown who had the devices surgically implanted. In particular, the Exactech device was defectively designed in that the design of the implant was prone to friction between the metal surfaces and to early failure, causing serious and permanent injuries.

72. At all times herein mentioned, the Exactech Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective and unreasonably dangerous condition at the time it left Defendants' possession.

73. At all times herein mentioned, the Exactech Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without

substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

74. At all times herein mentioned, the Exactech Device's unsafe, defective, and unreasonably dangerous condition was a proximate, producing or other legal cause of injury to Plaintiff Robert B. Brown.

75. At all times herein mentioned, the Exactech Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

76. The design of the Exactech Device was defective at the time the device was first offered for sale in the United States and remained defective throughout the entire time the product was sold in the United States.

77. Robert B. Brown's injuries resulted from use of the Exactech Device that was both intended and reasonably foreseeable by Defendants.

78. At all times herein mentioned, the Exactech Device posed a risk of danger inherent in its design which outweighed the benefits of that design.

79. At all times herein mentioned, the Exactech Device was defective and unsafe, and Defendants knew or had reason to know that it was defective and unsafe, especially when used in the form and manner as provided by Defendants.

80. Defendants knew, or should have known, that all times herein mentioned that the Exactech Device was in a defective condition as a result of its design,, and was and is unreasonably dangerous and unsafe.

81. At the time of the implantation of the Exactech Device into the Plaintiff Robert B. Brown, the product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

82. Defendants, with this knowledge, voluntarily designed its Exactech Device in a dangerous condition for use by the public and, in particular, Robert B. Brown.

83. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

84. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Robert B. Brown, in particular, and Defendants are therefore strictly liable for the injuries sustained by Brown.

85. At all times material to these claims, there was a safer alternative design that was both technologically and economically feasible which would have prevented or substantially reduced the risk of Plaintiff Robert B. Brown's injuries without substantially impairing the device's utility.

86. As a direct and proximate result of Defendants' placement of the defective Exactech Devices into the stream of commerce, Plaintiff Robert B. Brown experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished

enjoyment of life. Plaintiff also needed a revision surgery to replace the device, which carried the attendant risks of complications and death from such further surgery.

87. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

FOURTH CLAIM FOR RELIEF

D. STRICT LIABILITY-MANUFACTURING DEFECT

88. Plaintiff Robert B. Brown hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

89. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Exactech Devices.

90. At all times herein mentioned, the Exactech Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective and unreasonably dangerous condition at the time it left Defendants' possession.

91. At all times herein mentioned, the Exactech Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

92. The Exactech Device that was surgically implanted in Plaintiff Robert B. Brown was defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could fail early in patients thereby giving rise to physical injury, pain and suffering, debilitation and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

93. As a direct and proximate result of Defendants' placement of the defective and unreasonably dangerous Exactech Devices into the stream or commerce, Brown has suffered and will continue to suffer substantial damages.

FIFTH CLAIM FOR RELIEF

E. FRAUD

94. Plaintiff Robert B. Brown hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

95. At the time Defendants manufactured, designed, marketed, sold and distributed the Exactech Device, they had knowledge of the dangers metal on-metal hip implant devices posed to their recipients. Further, Defendants had knowledge of the physical injury, pain and suffering, debilitation, and need for revision surgeries and subsequent complications that the Exactech device imposed on patients receiving the devices.

96. The dangers associated with the use of metal-on-metal and the subsequent physical injury, pain and suffering, debilitation, and the need for revision surgeries and the subsequent complications were, and are, material facts.

97. Defendants knowingly, intentionally, and with reckless disregard of the true facts made false representations of material facts and omitted material facts to Plaintiff and/or his doctor, including, but not limited to, claims that the Exactech Device was safe, effective and fit for use as a hip replacement device.

98. Defendants' misrepresentation and omission of known facts were intended to induce Brown and/or his doctor to purchase and use the Exactech Device.

99. Plaintiff Robert B. Brown and/or his doctor relied on Defendants' misrepresentations of material facts regarding the safety, effectiveness and fitness of the Exactech Device for use as a hip replacement device. Brown and/or his doctor further relied on Defendants to provide them with information about the dangers of the Exactech Device, and not to conceal information they had about such dangers. Had Brown known the risks associated with the use of the Exactech Device, he would not have agreed to the use of the device to treat his condition.

100. Plaintiff Robert B. Brown and/or his doctor reasonably relied on the information provided by Defendants in deciding whether to obtain, implant, and retain the Exactech Device.

101. As a direct and proximate result of reliance on the Defendants' misrepresentations, Brown has suffered and will suffer damages as described herein.

102. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

SIXTH CLAIM FOR RELIEF

F. NEGLIGENT MISREPRESENTATION

103. Plaintiff Robert B. Brown hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

104. Defendants made misrepresentations and omissions of material facts, including, but not limited to:

a. That Plaintiff Robert B. Brown's implant was fit for its intended use;

b. That Plaintiff's Exactech implant was of merchantable quality;

c. That Plaintiff's Exactech implant was safe and efficacious in the treatment of Plaintiff's medical condition;

d. That Plaintiff's implant would function as intended when necessary;

105. Defendants omitted to reveal material facts, including, but not limited to:

a. That Plaintiff Robert B. Brown's Exactech implant was defective, such that it would fail to function as intended;

b. That Plaintiff Robert B. Brown's Exactech implant presented a risk of injury and harm in its ordinary and intended uses; and

c. That Plaintiff's Exactech implant was unreasonably dangerous.

106. These representations and/or omissions were false and misleading at the time they were made.

107. False information about the characteristics and safety of the Exactech hip implant device was supplied by Defendants for the guidance of others.

108. Defendants did not exercise reasonable care or competence in obtaining or communicating this information, but rather negligently and carelessly made the foregoing misrepresentations without a basis.

` 109. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Robert B. Brown that there was no reasonable basis for making said representations herein.

110. When Defendants made these representations, they knew or should have known them to be false.

111. When Defendants made the foregoing representations, they intended to induce Plaintiff Robert B. Brown and/or his doctor to select the Exactech hip device for use in Brown's arthroplasty surgery.

112. In reliance upon the foregoing misrepresentations by the Defendants, Plaintiff Robert B. Brown was induced to and did subject himself to the use of the Exactech Device. If Plaintiff had known of the true facts, he would not have taken such action and risk. Plaintiff's reliance on Defendants' misrepresentations and omissions was reasonable because said representations were made by individuals and entities in a position to know the true facts.

113. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff Robert B. Brown has suffered and will continue to suffer injury, expense and economic loss as previously described.

SEVENTH CLAIM FOR RELIEF

G. BREACH OF EXPRESS WARRANTY

114. Plaintiff Robert B. Brown restates each and re-alleges every allegation set forth above with the same force and effects as it set forth herein and repeated in full.

115. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Exactech Devices.

116. Defendants expressly warranted that the Exactech Device was safe and effective hip replacement system.

117. The Exactech Devices placed into the stream of commerce by Defendants did not conform to these express representations because they failed early, as did Brown's, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

118. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Exactech Devices, Plaintiff Robert B. Brown has suffered and will continue to suffer substantial damages.

119. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

EIGHTH CLAIM FOR RELIEF

H. BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

120. Plaintiff Robert B. Brown restates each and re-alleges every allegation set forth above with the same force and effects as it set forth herein and repeated in full.

121. Defendants are in the business of designing, manufacturing, and/or supplying and/or placing into the stream of commerce the Exactech Devices for consumers.

122. By placing the Exactech Devices into the stream of commerce, Defendants impliedly warranted that they were merchantable and fit and safe for their intended use.

123. By placing the Exactech Device into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.

124. The Exactech Device places into the stream of commerce by Defendants was defective and accordingly, was not fit, safe, or merchantable for its intended use.

125. The defects in the Exactech Device designed, manufactured and/or supplied and/or placed into the stream of commerce by Defendants, were present at the time the product left Defendants' control.

126. Defendants breached the implied warranty for the Exactech Device because said product was defective and unmerchantable.

127. Plaintiff Robert B. Brown was a foreseeable user of the Exactech Device designed, manufactured and/or supplied and placed into the stream of commerce by Defendants.

128. As a direct and proximate result of Defendants' breach of these implied warranties, Plaintiff has suffered and will continue to suffer injury, expense and economic loss as previously described, rendering Defendants liable for said damages.

129. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

VI. ACTUAL AND EXEMPLARY DAMAGES

130. Plaintiff Robert B. Brown adopts by reference and incorporates herein the allegations set forth above.

131. As described herein, Robert B. Brown has sustained damages and losses as a result of the wrongful and tortious conduct of Defendants, for which Defendants are jointly and severally liable. Plaintiff hereby requests the Court and Jury to determine the amount of loss he has incurred in the past and will incur in the future, not only from a financial standpoint but also in terms of good health and freedom from pain and worry. There are certain elements of damages, provided by law, that Plaintiff is entitled to have the Jury in this case separately consider to determine the sum of money for each element that will fairly and reasonably compensate Plaintiff for his injuries, disabilities, damages, and losses incurred and, in reasonable probability, to be incurred in the future. From the date of the incident until the time of trial, those elements of past damages to be considered separately and individually are as follows:

a. The physical pain that Robert B. Brown has suffered from the date of his injury until the time of trial;

b. The mental anguish that Robert B. Brown has suffered from the date of his injury until

the time of trial;

c. The amount of reasonable medical expenses, necessarily incurred in the care and treatment of Robert B. Brown's injuries from the date of his injury until the time of trial;

d. The physical incapacities, disabilities and impairments suffered by Robert B. Brown, and the resulting inability to do those tasks and services that he would have ordinarily been able to perform, from the date of his injury until the time of trial; and

e. The disfigurement of Robert B. Brown from the date of his injury until the time of trial.

132. From the time of the trial of this case, those elements of future damages to be separately considered which Plaintiff Robert B. Brown will, in reasonable probability, sustain in the future beyond trial are the following:

a. The physical pain that Robert B. Brown will suffer beyond the time of trial;

b. The mental anguish that Robert B. Brown will suffer beyond the time of trial;

c. The reasonable value of medical expenses that will necessarily be incurred in the care and treatment of Robert B. Brown's injuries beyond the time of trial;

d. The physical incapacities, disabilities and impairments suffered by Robert B. Brown, and the resulting inability to do those tasks and services that he would have ordinarily been able to perform, beyond the time of trial; and

e. The disfigurement of Robert B. Brown beyond the time of trial.

133. Plaintiff Robert B. Brown is also entitled to recover pre-judgment and post-judgment interest as allowed by law, for which Plaintiff hereby bring suit to recover together with court costs and any other relief to which he is entitled.

134. In addition to his actual damages, as outlined above, Plaintiff Robert B. Brown is also entitled to recover exemplary damages from Defendants under Chapter 41 of the Texas Civil Practice and Remedies Code.

135. Specifically, the acts and omissions of Defendants described herein constituted, fraud, malice, and/or gross negligence. Consequently, Plaintiff is entitled to have the Jury consider and award exemplary damages against Defendants.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays as follows:

a) That process issue according to law;

b) That Defendants be duly served and summoned to appear and answer herein, and that after due proceedings are had, that there be judgment in favor of Plaintiff and against Defendants for the damages set forth below, along with court costs, pre-judgment and post-judgment interest;

1. pain and suffering (past and future);
2. wage loss (past and future);
3. loss of earnings and loss of earning capacity;
4. medical expenses (past and future);
5. loss of enjoyment of life (past and future);
6. mental anguish and distress (past and future);
7. disfigurement (past and future);
8. physical impairment (past and future);

9. attorney's fees;

10. punitive or exemplary damages in such amounts as may be proven at trial; and

11. for all such other relief to which Plaintiff may show himself justly entitled.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all claims in this action.

Respectfully Submitted,

THE ERWIN LAW FIRM

s/ Jacob E. Erwin
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 24th day of August, 2017, I electronically filed the foregoing with the Clerk of the Northern District of Texas using the CM/ECF system and placed in regular U.S. Mail with sufficient postage and delivered to the addresses below:

Donna Edwards, Esq.
Attorney for Defendants
2320 NW 66th CT
Gainesville, FL 32653

William B. Jakes, III
Howell & Fisher, PLLC
Court Square Building, 300 James Robertson Parkway
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/s/ Jacob E. Erwin
JACOB E. ERWIN, BPR # 020728